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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/613,076	07/07/2003	Steven M. Ruben	PZ034P1C2	8540

22195 7590 04/03/2006

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EXAMINER	
DANG, IAN D	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 04/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/613,076	NI ET AL.	
	Examiner	Art Unit	
	Ian Dang	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25-48* is/are pending in the application.

4a) Of the above claim(s) *48* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *25-47* is/are rejected.

7)☒ Claim(s) *29,34 and 43* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____. 1/23/06
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

Claim 29 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claims 27 and 26. See MPEP § 608.01(n).

Claims 34 and 43 are objected to because of the following informalities: periods are missing at the end of the claims. Appropriate correction is required.

Election/Restrictions

Applicant's election of Group 72 in the reply filed on January 23, 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Newly submitted claim 48 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the method of detecting the polypeptide is distinct from the isolated antibody because the antibody as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the antibody can be used as a method of treatment.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 48 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Inventorship

In view of the papers filed January 23, 2006, the inventorship in this nonprovisional application has been changed by the deletion of Jian Ni, Reinhard Ebner, Paul E. Young, Charles E. Birse, Kenneth C. Carter, and George Komatsoulis.

The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of Office records to reflect the inventorship as corrected.

Claim Rejections - 35 USC § 101/112

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The examiner is using the following definitions in evaluating the claims for utility.

"Specific" – A utility that is specific to the subject matter claimed. This contrasts with a general utility that would be applicable to the broad class of the invention.

"Substantial" – A utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities.

"Credible" – Credibility is assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record that is probative of the Applicant's assertions. That is, the assertion is an inherently unbelievable undertaking or involves implausible scientific principles.

See also the MPEP at § 2107-2107.02.

Claims 25-47 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific, substantial, and credible utility or, in the alternative asserted utility or a well established utility.

Claims 25-45 are drawn to an antibody or fragment thereof drawn to a polypeptide of encoded by SEQ ID NO 48, and claims 46-47 to a cell and a hybridoma producing the antibody. Therefore, the antibody derives its utility from the polypeptide. If the polypeptide does not have utility, the antibody and cells producing the antibody do not have utility as well.

SEQ ID NO:48 is disclosed as HFXHC41 with an amino acid sequence of 1308 residues (table 1, page 72) and has several immunogenic epitopes (page 16).

Sequence alignment performed at the USPTO indicates that the SEQ ID NO. 48 share 34% identity over CD 44 (AAB00792) and 45% identity over cartilage linked protein (CAA35462) (see alignment attached). Without a high degree of sequence similarity, it is not deemed reasonably to support one skilled in the art whether the biochemical activity of the polypeptide would be the same as that of such similar known protein. It is known for proteins that even a single amino acid change or mutation can destroy the function of the biomolecule in many instances. The effects of these changes are largely unpredictable as to which ones have a significant effect versus not. Therefore sequence homology results in an unpredictable and therefore unreliable correspondence between the claimed biomolecule and the indicated similar biomolecule of known function and therefore lacks support regarding utility.

The polypeptide encoded by SEQ ID NO: 48 is not supported by a specific utility because the exact function of the protein is not known. Applicants list a number of possible uses for CD44 disclosed in the application, such as its role for leukocyte migration or in the regulation of tumor metastasis (page 13). But Applicants fail to assert a specific utility for the

claimed polypeptide encoded by SEQ ID NO: 48. None of the utilities is specifically linked to the polypeptide encoded by SEQ ID NO: 48.

The asserted utility disclosed in the specification is not substantial because the disclosed uses of the protein are generally applicable to a wide variety of proteins. The polypeptide is not supported by a substantial utility because no substantial utility has been established for the claimed subject matter. For instance, the specification discloses that the polypeptide is involved in inflammation or hematopoiesis (page 13). However, this utility depends on the activity/function of the polypeptide, and on the elucidation of the association of diseases therewith, which are yet to be discovered through further research. The apparent need for such research indicates that the polypeptide is not disclosed as to a currently available or substantial utility.

The antibody to the polypeptide encoded by SEQ ID NO: 48 and cells producing the antibody have no utility because the polypeptide has no utility.

Claims 25-47 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial, credible utility, asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 25, 27-38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not

described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This is a new matter rejection. Although Applicants has provided detailed indications for support for the amended claims, the specification does not meet the limitations of claim 25. In particular, the specification does not provide support for an antibody binding at least 30 or 50 contiguous amino acid residues specific for SEQ ID NO: 48. Since claims 27-~~39~~ 38 are dependent on claim 25, they also contain new matter.

Conclusion

No claim is allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ian Dang whose telephone number is (571) 272-5014. The examiner can normally be reached on Monday-Friday from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ian Dang
Patent Examiner
Art Unit 1647
March 27, 2006

Marianne P. Allen

MARIANNE P. ALLEN
PRIMARY EXAMINER 3/30/06

AU1647

ALIGNMENT OF SEQ ID NO: 48

>gi|11141887|ref|NP_068599.1| brain link protein-1 [Homo sapiens]
gi|20987412|gb|AAH29864.1| Brain link protein-1 [Homo sapiens]
gi|55959666|emb|CAI13055.1| hyaluronan and proteoglycan link protein 2 [Homo sapiens]
gi|11094311|dbj|BAB17669.1| brain link protein-1 [Homo sapiens]
gi|20177844|sp|Q9GZV7|HPLN2_HUMAN Hyaluronan and proteoglycan link protein 2 precursor (Brain link protein 1)
gi|11094293|dbj|BAB17662.1| brain link protein-1 [Homo sapiens]
Length=340

Score = 313 bits (803), Expect = 5e-84
Identities = 151/330 (45%), Positives = 207/330 (62%), Gaps = 11/330 (3%)

```
Query  22   YTLDHDRAIHIQAENGPHLLVEAEQAKVFSHRGGNVTLPCKFYRDPTAFGSGIHKIRIKW  81
            +T+ H       +  GPH L+       + SHRG   ILPC     P ++       +++W
Sbjct  18   FTIFHKAQGDPASHPGPHYLLPPIHEVIHSHRGATATLPCVLGTIPPSY-------KVRW  70

Query  82   IKLISDYLKEVDVFVSMGYHKKIYGGYQGRVFLKGGSDSDSASLVITDLTLEDYGRYKCEV  141
            +K+    L+E  + ++ G H + YG   GR  ++ G   DASLVI  + LED GRY+CE+
Sbjct  71   SKVEPGELREILILITNGLHARGYGPLGGRARMRRGHRLDASLVIAGVRLEDEGRYRCEL  130

Query  142  IEGLEDDTVVVALDLQGVVFPYFPRLGRYNLNFHEAQQACLDQDAVIASFDQLYDAWRGG  201
            I G+ED++V + L L+GVVFPY P  GRY  N++EA+QAC +QD  +A++ QLY AW  G
Sbjct  131  INGIEDESVALTLSLEGVVFPYQPSRGRYQFNYYEAKQACEEQDGRLATYSQLYQAWTEG  190

Query  202  LDWCNAGWLSDGSVQYPITKPREPCGGQNTVPGVRNYGFWDKDKSRYDVFCFTSNFNGRF  261
            LDWCNAGWL +GSV+YP+    R PCGG+    PG+R+YG  D+ + RYD FCFTS   G+
Sbjct  191  LDWCNAGWLLEGSVRYPVLTARAPCGGRGR-PGIRSYGPRDRMRDRYDAFCFTSALAGQV  249

Query  262  YYLIHPIKLTYDEAVQACLNDGAQIAKVGQIFAAWKILGYDRCDAGWLADGSVRYPISRP  321
            +++  P +LT  EA  AC   GA +AKVG ++AAWK  G D+CD GWLADGSVR+PI+ P
Sbjct  250  FFV--PGRLTLSEAHAACRRRGAVVAKVGHLYAAWKFSGLDQCDGGWLADGSVRFPITIP  307

Query  322  RRRCSP-TEAAVRFVGFPDKKHKLYGVYCF  350
            R RC    +  VR  GFP  +   YG YC+
Sbjct  308  RPRCGGLPDPGVRSFGFPRPQQAAYGTYCY  337
```

ALIGNMENT OF SEQ ID NO:48

>gi|1332377|gb|AAB00792.1| adhesion receptor CD44
Length=277

 Score = 56.2 bits (134), Expect = 2e-06
 Identities = 30/88 (34%), Positives = 45/88 (51%), Gaps = 2/88 (2%)

```
Query  166  RLGRYNLNFHEAQQACLDQDAVIASFDQLYDAWRGGLDWCNAGWLSDGSVQYPITKPREP  225
            R G+Y L + EA+  C  +    +A++ QL  A + G   C AGW++ G V YPI KP
Sbjct  43   RSGKYKLTYAEAKAVCEFEGGHLATYKQLEAARKIGFHVCAAGWMAKGRVGYPIVKPGPN  102

Query  226  CGGQNTVPGVRNYGFWDKDKSRYDVFCF  253
                 I  G+ +YG        R+D +C+
Sbjct  103  XXFGKT--GIIDYGIRLNRSERWDAYCY  128


 Score = 50.8 bits (120),  Expect = 8e-05
 Identities = 29/85 (34%), Positives = 42/85 (49%), Gaps = 1/85 (1%)

Query  269  KLTYDEAVQACLNDGAQIAKVGQIFAAWKILGYDRCDAGWLADGSVRYPISRPRRRCSPT  328
            KLTY EA   C  +G  +A   Q+ AA KI G+  C AGW+A G V YPI +P
Sbjct  48   KLTYAEAKAVCEFEGGHLATYKQLEAARKI-GFHVCAAGWMAKGRVGYPIVKPGPNXXFG  106

Query  329  EAAVRFVGFPDKKHKLYGVYCFRAY  353
            +  +   G    + + +  YC+  +
Sbjct  107  KTGIIDYGIRLNRSERWDAYCYNPH  131
```